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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---------------------------|-------------|----------------------|---------------------|------------------|
| 09/956,004 | 09/20/2001 | Patrick J. Dillon | PB324D1 | 1504 |
| 22195 | 7590 | 11/06/2003 | EXAMINER | |
| HUMAN GENOME SCIENCES INC | | | LY, CHEYNE D | |
| 9410 KEY WEST AVENUE | | | ART UNIT | PAPER NUMBER |
| ROCKVILLE, MD 20850 | | | 1631 | |

DATE MAILED: 11/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------|--------------------------------|---------------------|
| Advisory Action | Application No. | Applicant(s) |
| | 09/956,004 | DILLON ET AL. |
| | Examiner Cheyne D Ly | Art Unit 1631 |

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 10 September 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) The period for reply expires 3 months from the mailing date of the final rejection.
- b) The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. The proposed amendment(s) will not be entered because:
 - (a) they raise new issues that would require further consideration and/or search (see NOTE below);
 - (b) they raise the issue of new matter (see Note below);
 - (c) they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 - (d) they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: ____.

3. Applicant's reply has overcome the following rejection(s): See Continuation Sheet.
4. Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. The a) affidavit, b) exhibit, or c) request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. For purposes of Appeal, the proposed amendment(s) a) will not be entered or b) will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: 34-39, 41, and 64.

Claim(s) objected to: ____.

Claim(s) rejected: 40 and 42.

Claim(s) withdrawn from consideration: ____.

8. The proposed drawing correction filed on _____ is a) approved or b) disapproved by the Examiner.
9. Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. Other: _____

Continuation of 3. Applicant's reply has overcome the following rejection(s): Claim 38 has been amended to read "fully complementary to the entirety of the nucleotide sequence of claim 34," which causes said claim to overcome the 35 U.S.C. § 112, Second Paragraph and § 102(e)(2) rejections. Applicants' argument and pointed to support for claims 35 and 36 have been fully considered and found to be persuasive; therefore, claim rejections under 35 U.S.C. § 112, First Paragraph, as directed to claims 35 and 36 have been overcome.

Continuation of 5. does NOT place the application in condition for allowance because:

CLAIM REJECTIONS - 35 U.S.C. § 112, SECOND PARAGRAPH

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 40 and 42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. This rejection is maintained with respect to claims 40 and 42, as recited in the previous office action mailed June 10, 2003.

4. Applicants argue with regard to the metes and bounds of the instant claims, the examples of operable association is disclosed in the specification, i.e., attached by covalent linkage, as the disclosed fragment of an E. coli pathogenicity island. It is acknowledged that Applicants disclose by way of Example 4, page 42, [0173], lines 8-11, wherein a polypeptide is produced and it is "covalently linked" to the carboxyl terminus of said polypeptide. Applicants' argument and the instant specification have been acknowledged and found to be unpersuasive due to said argument and disclosure do not help Applicants overcome the vague and indefinite issue caused by the phrase "operably associated" in the instant claims.

CLAIM REJECTIONS - 35 U.S.C. § 112, FIRST PARAGRAPH

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 40 and 42 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

7. This rejection is maintained with respect to claims 40 and 42, as recited in the previous office action mailed June 10, 2003.

8. Applicants' pointed to support ([0068] and [0069]) has been fully considered and found to be unpersuasive due to said pointed to support does not support that the specification discloses the operable association of a "heterologous" regulatory sequence, which is considered to be new matter..



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